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ORALS

TCT-97

Long term follow up of 134 patients with non valvular atrial fibrillation and contraindications to oral anticoagulation therapy, treated with the Ampatzer Cardiac Plug Device for left atrial appendage occlusion

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Background: Left atrial appendage occlusion with the Amplatzer Cardiac Plug Device (ACP) (St Jude Medical, Minneapolis, MN) for non valvular atrial fibrillation(NVAF) and contraindications to oral anticoagulant therapy (OAC) is showing to be feasible and safe but there is lack of data as for the long term follow up.
Methods: We report the follow up of 134 patients treated with ACP device from 1/2009 to 12/2012 in two Italian centers. Most patients received short-term (1-3 months) dual antiplatelet therapy following the procedure and single antiplatelet therapy thereafter. Follow up was carried out by clinical visits or phone contact at 1, 6 and 12 months and yearly thereafter. A total of 93(72.6%) patients received imaging follow-up 6 months after the procedure either by transesophageal echography(TEE) or by cardiac CT scan. The presence of device thrombosis and residual leak were evaluated.
Results: Mean age and median CHADS2 were 76±8 years and 3 respectively. The procedure was successful in 96% of the patients. Main complications were pericardial effusion (4.4%) with 2 cases of cardiac tamponade (1.4%), 1 hemorragic stroke and 1 TIA. Median follow up was 22 months (range 1.4 – 53.6). The longest follow up was 4 years for 4 patients. 26 patients had a follow up of 3 years. 110 patients had a follow up of >=12 months. The rates of death, stroke, TIA and systemic embolism at follow-up, were 5.5%, 1.5%, 2.3% and 0%, respectively. The presence of peri device leak was observed in 5.4% of patients at 6-months imaging follow-up. No massive leak was observed. There was one case of device thrombosis that resolved after 1 month of anticoagulation. The expected stroke rate was 8.6% versus an observed stroke rate of 1.5% ($p<0.01$).
Conclusions: Our follow up of patients treated with ACP device for NVAF and contraindications to OAC demonstrates the efficacy of the procedure in preventing stroke over a long time period (110 pts followed for >1 year), with a significant reduction of the risk of stroke as compared with the expected incidence. The imaging follow-up showed low incidence of significant residual leaks. We also confirm the feasibility and safety of the LAAO procedure.

TCT-98

Largest Single-Center Experience of Percutaneous Left Ventricular Transapical Access for Structural Heart Disease Interventions

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Background: Percutaneous left ventricular transapical access (TA) can be utilized for a multitude of diagnostic and interventional procedures in structural heart disease (SHD). With advancements in imaging and device technology, applicability of this approach is expanding. We present our growing experience in utilizing TA for structural heart interventions.
Methods: We evaluated patients at our center, from April 2008 to June 2013, who presented for SHD intervention. Ninety four TA were performed in 80 consecutive patients (54 males, 71±30 years) with 4 patients having double TA during the same intervention and 10 patients having repeat TA during subsequent SHD interventions (double TA n=13). Since August 2010, computed tomographic angiography (CTA)/fluoroscopy fusion imaging (HeartNavigator, Philips, Netherlands) has been used to guide TA puncture.
Results: All TA were successfully performed for the following interventions: 74 mitral paravalvular leak (PVL) closure, 6 aortic PVL closure, 14 left ventricular pseudoaneurysm (LVPA) closure, 2 ventricular septal defect closure, 8 mitral transcatheter valve-in-valve implantations, and 10 combined procedures. Average initial/final sheath sizes were 6F and 7F (range 5F-12F). TA was closed using an Amplatzer Ductal Occluder n=86, Amplatzer Vascular Plug II n=3, Muscular VSD Occluder n=3, and coils n=2. Complications occurred in 13 cases (14%): hemothorax n=5, pericardial effusion/tamponade n=1; persistent access site bleeding requiring surgical closure n=2, non-fatal device migration n=3 (2 ventricular, 1 epicardial requiring surgical closure), and death n=2. One death occurred in a patient with suprasystemic pulmonary hypertension developing pulseless electrical activity and one death occurred after PVL closure in the setting of untreated critical aortic stenosis and epicardial device migration. There was no significant difference in complications associated with use of fusion imaging (with 10% vs without 17.6%, p=0.29).
Conclusions: TA is useful in multiple SHD interventions. Despite fusion imaging, complications still occur. More reliable TA closure devices may further improve the safety and generalizabilty of this approach for more complex SHD interventions.

TCT-99

Long-term recurrent ischemic event rates after percutaneous closure of patent foramen ovale in patients with paradoxical embolism

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Background: Patients with a patent foramen ovale (PFO) and a history of paradoxical embolism are at risk to suffer from recurrent events even if the PFO was closed percutaneously. This study investigated the long-term results of a high-volume center.
Methods: PFOs were closed in patients with a history of at least one assumed paradoxical embolism (TIA, stroke or peripheral embolism) or a diving accident. The type of closure device was chosen due to availability and operator's decision. All patients were prescribed a dual antiplatelet therapy (aspirin and clopidogrel) for the first 6 months after the procedure. Echocardiographic studies were performed at 4 weeks and 6 months after the index procedure. Patients were evaluated for residual shunts and the incidence of potential adverse events. All patients were followed annually through office visits, questionnaires and phone calls, or by contacting the referring physicians.
Results: Between August 1998 and December 2012 percutaneous closure of patent foramen ovale was performed in 2831 patients. The mean age of patients was 50 ± 13 years. 55% were male (n=1551). Indication for PFO-closure was a history of migraine (n=481), peripheral embolism (n=55), diving accident (n=36) or cryptogenic cerebral ischemia (TIA in n=1334 or stroke in n=1666). 563 patients (19.9%) suffered from recurrent neurological events before percutaneous PFO-closure. We used 23 different types of closure devices. The most commonly used occluders were the Amplatzer (n=914), the Helex (n=470), the Premere (n=409) and the CardioSEAL-STARflex device (n=303). Within a total of 8,873 patient years of follow-up (mean follow-up duration: 38 months), there were 89 recurrent embolic events. This compares to an annual event rate of 1.0%. 29 patients suffered from recurrent TIA, and in 54 patients an ischemic strokes occurred. In 6 patients peripheral embolic events occurred. In 122 patients (4.3%) a second device implantation was performed to close a residual shunt.
Conclusions: The results of this study represent the clinical experience of a European high-volume center in PFO-closure and show a favorable and much lower annual recurrent event rate compared to previously published randomized trials.

TCT-100

Effect of Intra cardiac echocardiography and yearly operator volume on Length of Stay and Cost of Care for Percutaneous Closure of Atrial Septal Defects and Patent Foramen Ovale: A Perspective of Last Decade

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Background: We assessed the predictors of length of hospital stay (LOS) and cost of care related to percutaneous closure of ASD and PFO closure.
Methods: We examined the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample (NIS) database from 2001 to 2010 using ICD 9-CM code for percutaneous ASD/PFO closure (35.52). Only adult (age > 18 year) patients with ASD/PFO (ICD 9-CM - 745.5) were included in study. We could not differentiate between ASD and PFO closure due to the same ICD9 code for both procedures. NIS is represents 20% of all US hospitals. Cost to charge ratio files were merged with NIS to calculate cost of care. Cost was adjusted for inflation in reference to 2010. Comorbid conditions were defined by Charlson's Comorbidity Index (CCI). Hierarchical multilevel regression models were generated to determine independent predictors of LOS and cost of care.
Results: Total of 7,107 (weighted n=34,990) percutaneous ASD/PFO closure procedures were analyzed. Average LOS and cost of care for percutaneous ASD/PFO closure were 2.63±0.06 days and $16,635±225, respectively. LOS was increased (days, 95% CI, P-value) with presence of any complication (+2.47 days, 2.14-2.80, P 2 (+1.84 days, 1.48-2.20, P<0.001). Decrease in LOS was associated with use of higher operator volume tertile(-2.58 days, -3.04 - -2.12, P2) (1.17, 1.12-1.22, P<0.001). Decrease in cost was associated with higher annual operator volume tertile (0.84, 0.08 - 0.88, P<0.001).